Risk Management and Food Safety

FDA’s Role in Ensuring Safe Food: Discussion Forum

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Risk Management for Homeland Security and Enhancing Food Safety

“Ultimately, homeland security is about effectively managing risks to the Nation’s security”
Quadrennial Homeland Security Review 2010

“Apply the recommended risk-based approach to the management of all food hazards”
Suggested Directions for Improving the FDA’s Food Safety Management Committee on the Review of the Food and Drug Administration’s Role in Ensuring Safe Food
Risk Management Requirement


- “Until (a uniform) methodology is in place, it will be impossible for DHS to make a determination of relative risks that could inform spending decisions.”
- “(DHS) components apply risk management in ways that are neither consistent nor comparable. The degree to which DHS uses common metrics, criteria, and approaches remains a management challenge.”
- “As DHS’s individual components begin to mature in their risk management efforts, the need for consistency and coherence becomes even greater. Without it, the prospects increase for efforts to fragment, clash, and work at cross purposes.”

FDA: Committee on the Review of the FDA’s Role in Ensuring Safe Food

- “Although the FDA is to be commended embracing classic tools of risk assessment and management, it currently lacks a comprehensive, systematic vision for a risk-based food safety system.”

The Decision Context for DHS

DHS spends billions each year on activities ranging from:
- screening people, baggage, and cargo at air, land and sea ports;
- patrolling the borders and coastline;
- protecting critical infrastructure and key resources; and
- preparing for, responding to, and assisting with the recovery from natural and man-made disasters.

How much should be spent on these distinct activities?
- FDA: Consumer perception, cost, controllability, public acceptance, environmental effects, and market impacts
DHS Office of Risk Management & Analysis

- Founded in 2007 as part of the National Protection and Programs Directorate
- Authority derived from DHS Delegation 17001
  - Lead DHS efforts to establish a common framework to address the overall management and analysis of homeland security risk
  - Develop systematic, rigorous risk analysis methodologies and computational capabilities to be used by all DHS Components to assess and quantify risk

Risk Governance and the DHS Risk Steering Committee (RSC)

- Established in 2007 to serve as a governing body to coordinate DHS risk management initiatives
  - Enhances DHS capabilities to employ effective risk management strategies and conduct mission-specific risk analyses
- Meets regularly
  - Tier II quarterly meetings
  - Tier III monthly meetings
  - Includes Featured Risk Practice Series briefings
- Established working groups for specific projects
  - Integrated Risk Management Framework
  - Risk Lexicon
  - Risk Assessment Process for Informed Decision-making (RAPID)
A Capability Approach to Mature DHS Integrated Risk Management

RMA and the RSC are committed to improving the state of integrated risk management across the enterprise.

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DHS Risk Lexicon

**Purpose**

Establish and make available a comprehensive list of structured words, terms, and meanings relevant to the practice of homeland security risk management and analysis.

**Deliverables**

- First DHS Risk Lexicon published September 2008
- Version 2 published September 2010
Integrated Risk Management Framework

**Purpose**
Use integrated risk management to inform strategies, processes, and decisions to enhance security and to work in a unified manner to manage risks to the Nation’s homeland security

**Deliverables**
- Interim Integrated Risk Management Framework published January 2009
- Secretary’s IRM Policy Statement signed May 2010
- Instructions and other implementation documents

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The DHS Risk Management Process

- DHS relies on a standardized risk management process to inform decision-making
- Risk analysis is part of risk management
- This process underpins DHS doctrine, guidance, policy and training
- It is intended for flexible, customized application based on the decision context and the roles and goals of the organization

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### Risk Management Guidelines

**Purpose**
Serve as technically accurate primers for DHS risk analysis practitioners on key homeland security risk management and analysis processes and techniques

**Deliverables**
- First set of guidelines published on DHS portals
- Developing Scenarios
- Designing Risk Assessments
- Analyzing Consequences
- Assessing Indirect Consequences in Risk Analysis
- Developing and Evaluating Alternative Risk Management Strategies
- Communicating Risk Analysis Results to Decision Makers

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### Integrated Risk Management Framework

*IRM Document Framework in DHS Directives System*

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#### Illustrative

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<th>INSTRUCTION</th>
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- DHS Risk Lexicon
- Risk Management Guidelines
- Risk Management Fundamentals
- Concept for IRM
Promote and Foster Partnerships

**Purpose**
Foster and promote the adoption of integrated risk management by building and nurturing partnerships across the homeland security enterprise

**Deliverables**
- Technical risk management capability workshops with FEMA Regions
- Risk management component of Comprehensive Preparedness Guide (CPG 101)
- Support to international partners
  - OECD - Future Risk Global Shocks Project
  - International Risk Governance Coordination Council
- Technical assistance

Risk Management Training Programs

**Purpose**
Provide risk analysts, program managers, operators and leaders with training on both the techniques and processes of risk management so that they may appropriately apply risk considerations to their decision making

**Deliverables**
- Developed publicly available risk management training with FEMA in 2009 – [www.learnaboutrisk.com](http://www.learnaboutrisk.com)
- Developing a Risk Management training program for DHS with the Curriculum Review Group

DHS Office of Risk Management and Analysis

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Advancing the safety, security and resilience of the Nation by leading an integrated national homeland security risk management effort